IN THE CLAIMS

1. (Previously allowed). A core formulation comprising,

(a) a first layer comprising pioglitazone hydrochloride or a pharmaceutically acceptable salt thereof as active ingredient,

(b) a core, at least a portion of which is enclosed by said first layer, comprising a biguanide as active ingredient.

2. (Previously allowed). The formulation as defined in claim 1 wherein said biguanide is metformin.

3. (Previously allowed). The formulation as defined in claim 2 wherein said pioglitazone hydrochloride is present in an amount ranging from 1 mg to 45 mg and, said metformin is present in an amount ranging from 10 mg to 4000 mg.

4. (Previously allowed). The formulation as defined in claim 2 which further comprises a biodegradable shell having a predetermined rate of degradation covering at least a portion of said first layer to provide a predetermined delay in the time period of release of at least said pioglitazone hydrochloride.

5. (Previously allowed). The formulation as defined in claim 2, wherein said pioglitazone hydrochloride and/or said metformin are present as biodegradable microspheres having a biodegradable shell coating and where said shell coating has a predetermined rate of degradation.

6. (Previously allowed). A method of administering pioglitazone hydrochloride and metformin to a mammal, which comprises treating the mammal with the formulation defined in claim 2.

7. (Previously allowed). A method for producing a controlled release formulation, which comprises:

(a) producing a hollow outer shell comprising a biodegradable material having a predetermined rate of degradation to provide a predetermined delay in the time period of release of the contents destined to be enclosed by said shell;

(b) inserting a core comprising metformin and having an outer layer comprising pioglitazone hydrochloride partially enclosing said core, into said hollow outer shell; and

(c) sealing said core within said hollow outer shell.

8. (Previously allowed). A method of producing a combined formulation of pioglitazone hydrochloride and metformin, which comprises:

(a) forming a core of the metformin; and

(b) depositing a layer of pioglitazone hydrochloride on at least a portion of a surface of said core.

9. (Previously allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises administering to the patient the formulation of claim 1 wherein said active ingredients are each present in an effective amount.

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10. (Currently amended). A pharmaceutical composition <u>in a single integral unit</u> ~~comprising~~ <u>consisting essentially of</u> an effective amount of pioglitazone hydrochloride combined with an effective amount of metformin.

11. (Currently amended). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the <u>integral</u> composition of claim 10.

12. (Currently amended). A pharmaceutical composition in a single integral unit ~~comprising~~ consisting essentially of an effective amount of pioglitazone hydrochloride combined with an effective amount of phenformin.

13. (Currently amended). A pharmaceutical composition in a single integral unit ~~comprising~~ consisting essentially of an effective amount of pioglitazone hydrochloride combined with an effective amount of buformin.

14. (Currently amended). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the integral composition of claim 12.

15. (Currently amended). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the integral composition of claim 13.

16. (Previously allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the composition of claim 1 wherein the biguanide is phenformin.

17. (Previously allowed). A method of treating diabetes mellitus in a patient in need thereof, which comprises, administering to the patient the composition of claim 1 wherein the biguanide is buformin.